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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/905,046	08/01/97	CASSELS	F

HM32/0612
JOHN F MORAN
OFFICE OF COMMAND JUDGE ADVOCATE
HQ USAMRDC
DEPARTMENT OF THE ARMY FORT DETRICK
FREDERICK MD 21702-5012

EXAMINER

DEVI, S

ART UNIT	PAPER NUMBER
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1641

2

DATE MAILED: 06/12/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
08/905,046Applicant(s)
F. Cassels et al.Examiner
S. DeviGroup Art Unit
1641☐ Responsive to communication(s) filed on _____.☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-11 ~~is~~ are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☐ Claim(s) _____ is/are rejected.☐ Claim(s) _____ is/are objected to.☒ Claims 1-11 are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
2. Effective 7 February 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 through 6, 8 and 9, drawn to a monoclonal antibody and a composition comprising the same, classified in class 530, subclass 387.9 and class 424, subclass 139.1
 - II. Claim 7, drawn to an assay for detecting the presence of organisms, classified in class 435, subclass 7.37 or 7.2
 - III. Claims 10 and 11, drawn to methods of treating and preventing an illness arising from infection using an antibody composition, classified in class 424, subclass 169.1Invention I is directed to a monoclonal antibody and a composition comprising the monoclonal antibody in a carrier. Invention II is directed to an *in vitro* assay and is patentably distinct from the product of inventions I and from the methods of invention III. Invention III is drawn to methods of treating and preventing an infection using the monoclonal antibody.

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Inventions I and III are related as a product and process of use of the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the method of invention III can be practiced with another materially different product such as an antibiotic or a specific antiserum or monoclonal antibodies via passive immunoprophylaxis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matters, restriction for examination purposes as indicated is proper.

4. Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

6. A telephone call was placed to Ms. Glenna Hendricks on 2 June 1998 to request for an oral election to the restriction requirement set forth above. Ms. Hendricks requested that a written restriction be sent to Mr. Charles Harris instead of Mr. John Moran at the same address. Ms. Hendricks' attention was also brought to the Office's requirement for compliance with Sequence Rules with regard to this application. Ms. Hendricks informed that the sequence rules would be complied within a week and that mailing of a Notice of Compliance with regard to Sequence submission was not necessary.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Devi whose telephone number is (703) 308-9347. The examiner can

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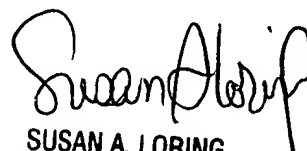
normally be reached on Monday to Friday from 8.00 am to 4.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



S. Devi, Ph.D.
4 June 1998



SUSAN A. LORING
PRIMARY EXAMINER
GROUP 1800-

1641